

# EXHIBIT B

**IN RE: Ashbrook v. Ethicon**  
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**THIS DOCUMENT RELATES TO The case of Ashbrook v. Ethicon**

**EXPERT REPORT OF DR. LENNOX HOYTE**

The following report is provided pursuant to my review of pertinent records for Iretta Ashbrook. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

1.

I am a female pelvic surgeon, formally trained in Female Pelvic Medicine and Reconstructive Surgery(FPMRS). I have personally trained fellows in my board approved FPMRS fellowship training program in Tampa, and also trained many residents in pelvic surgery techniques between 2005 and 2015, when I was founding director of the FPMRS fellowship program at the USF College of Medicine. I served on the faculty of OB/Gyn at Harvard Medical School – Brigham and Womens' Hospital in Boston, and started the division of Female Pelvic Medicine and reconstructive surgery at the USF Morsani College of Medicine in Tampa, Florida, where I served as Professor and Fellowship Director of the FPMRS program from 2006, until I left the University to start a private surgical practice in 2016. I also pioneered the field of MR based three-dimensional reconstruction of the female pelvic floor organs, and published many original peer-reviewed manuscripts in the area of 3D female pelvic floor anatomy. My Curriculum Vitae is attached as **Exhibit**

1. I personally perform about 350 pelvic surgical procedures annually, including robotic, open, and transvaginal procedures to address pelvic organ prolapse, urinary

and fecal incontinence, bladder and bowel control problems. I have personally performed over 1300 synthetic large-pore polypropylene retropubic sling procedures, over 500 Autologous Rectus Fascial (ARF) sling procedures, over 1500 sacrocolpopexies, and hundreds of native tissue prolapse repairs via vaginal and robotic laparoscopic routes. I have also explanted over 800 transvaginal mesh products via vaginal and laparoscopic robotic routes.

About fifty of the surgeries I currently perform annually are for the removal and/or revision of transvaginally placed mesh, due to complications like mesh related pain, dyspareunia, hyspareunia, erosion, extrusion, exposure, abscess formation, perforation of visceral organs, urinary retention, bowel and bladder dysfunction. I have personally explanted over 800 trans-vaginal mesh and sling products due to complications. From my personal experience with over three thousand female pelvic floor related surgeries, and my experience in training fellows and residents in pelvic surgery, it is my professional medical opinion that pelvic floor surgery is a skill to be painstakingly learned and products for pelvic floor repair cannot be universally marketed to all surgeons. I have never been a proponent of trocar-based transvaginally implanted mesh for pelvic organ prolapse repair, and I have never been a proponent of trans-obturator slings for stress urinary incontinence.

Approximately in 2002, when I served as a generalist OB/Gyn physician in Boston, I was approached by an engineer from Johnson and Johnson regarding my research in MR-based 3D pelvic reconstruction. As I recall, the engineer asked if I was interested in building 3D models to help understand the anatomy of the pelvic

floor related to pelvic reconstructive surgery. I opted not to follow up on the request, due to my other professional commitments. In the past, I have also attended sponsored cadaver training sessions, and was under consulting contracts with AMS and Bard Urological. In the past 10 years, I have also served as laboratory faculty for 2 cadaver dissection courses, one for Boston Scientific, and the other for Coloplast. I did not teach any transvaginal prolapse mesh placement techniques for either of these laboratory courses. I have also served as a surgical proctor for Intuitive Surgical, also giving lectures and running cadaver lab trainings to teach robotic sacrocolpopexy techniques. I have never taught transvaginal mesh placement techniques for prolapse repair or transobturator slings.

The only mesh procedures that I perform are abdominal (open and robotic) sacrocolpopexies, and the only types of incontinence slings that I place are large pore, low stiffness retropubic slings. I also place autologous fascial slings for women with stress urinary incontinence, who either refuse polypropylene implants, or have had exposures or erosion of previously implanted polypropylene mesh. I have never implanted a trans-obturator sling in a living woman, because of my belief that the transobturator approach requires sling passage through, and scarring into the levator, obturator, and adductor muscles, causing pain and irritative bladder symptoms during and after the healing process. I use the retropubic approach because sling passage is via the space of Retzius, and anchoring is through the tendons of the rectus abdominis muscles near the symphysis: in my experience, inevitable mesh shrinkage of up to 50%, and scarring into these tendons do not cause long term postoperative pain. In addition, with the large pore, low-stiffness

polypropylene retropubic sling, only a very small amount of synthetic mesh remains in direct contact with the vaginal wall, minimizing the size of the vaginal scar, minimizing the risk for scar pain and mesh exposure. Furthermore, I exclusively use large pore polypropylene slings, which come enclosed in plastic sheaths, designed to protect the sling material from the vaginal fluids and bacteria during placement, and also protect the pelvic tissues from friction of the polypropylene material during initial sling placement. The protective sheaths are removed after the sling is placed in its final position. Another reason that I use the retropubic pathway is that retropubic sling tension can be re-adjusted long after implantation via the space of Retzius, using endoscopic techniques.

I routinely follow all of my mesh-implanted patients annually with detailed vaginal examinations and symptom review. In my personal experience with placing approximately 1300 of the large pore, sheathed retropubic slings over the past 14 years, I have seen less than 10 cases where the retropubic sling eroded into the vagina or viscera.

I have never placed a kit-based transvaginal mesh for prolapse repair from any manufacturer, in any living patient, at any time. I have never been a proponent of trocar-based transvaginally implanted mesh for pelvic organ prolapse repair.

I currently place retropubic synthetic mesh slings for stress urinary incontinence, and have done so for over 14 years. I also perform autologous fascial sacrocolpopexy and autologous fascial retropubic sling procedures, in addition to other native tissue repairs, like anterior/posterior repairs, sacrospinous fixations, and uterosacral suspensions via vaginal and laparoscopic routes. I have never

placed a transvaginal synthetic sling from any manufacturer, in a living patient via the trans-obturator route.

I have also personally removed over 800 transvaginal mesh implants, including at least 200 transobturator slings, so determined from patient accounts, surgical operative notes and operating room determination of the sling path.

In my extensive personal experience with managing complications from anti-incontinence procedures, the main reasons for explanting transobturator slings is because of pain, pain with intercourse, groin pain, mesh exposure, as well as defecatory dysfunction, and the main reason for removing retropubic slings is mesh erosion into the vagina, urethra, or bladder. In my surgical practice, I have developed techniques for adjusting retropubic slings in case of urinary retention, and postoperative stress incontinence, and these therapies make retropubic sling removal unnecessary in cases of retention or persistent stress incontinence.

I have reviewed Instructions for Use ("IFUs") for Implanted products that I use throughout my career.

I have reviewed the general and product specific literature related to the Gynecare TVT-O product.

This, together with my substantial training and experience in Engineering, FPMRS, female pelvic surgery, and anatomy, gives me adequate experience to offer opinions about the Gynecare TVT-Obturator product.

#### **TVT-Obturator (TVT-O) METHOD OF IMPLANTATION**

For the Gynecare TVT-O sling, the IFU instructs the surgeon to use the “inside-out” approach. In this approach, the surgeon is instructed to mark the exit points of the sling tubes on the left and right thigh, lateral to the groin folds. Then, a 1 centimeter incision is made in the anterior vaginal wall under the urethra, 1 centimeter proximal to the urethral meatus. Blunt scissor dissection is then to be carried out under the vaginal mucosa at a 45 degree angle on the left and right. The mucosal dissection is carried to the body of the pubic bone, at the junction of the inferior pubic ramus. Then, an instrument called a “winged guide” is pushed through the dissected tunnel and into the obturator internus muscle. The winged guide is meant to be steer the sling through its course through the obturator internus muscle and groin tissues. The TVT-O sling comes enclosed in a plastic sheath, with each end of the sling fused to the sheath and a hollow plastic tube. The hollow plastic tube is threaded onto a curved needle, which is then passed through a groove in the winged guide, through the dissected vaginal tunnel, through the obturator internus muscle, and exiting on the skin of the inner thigh, lateral to the thigh folds, where the hollow tube is grasped and held with a clamp. Then the curved needle is withdrawn along with the winged guide, leaving the hollow plastic tube in its place of exit on the thigh skin. The hollow tube is pulled out of the thigh incision until the sling and sheath become visible on the inner thigh skin. This method of passing the sling arms is performed on the left and right sides, such that the ends of the hollow tubes are protruding through the thigh skin on the left and right. The tape is then supposed to be placed loosely under the under the urethra by pulling on the ends exiting on the thigh skin on the left and right. Once the tape is placed, the plastic sheaths are pulled

off of the sling material, and the sling arms are trimmed under the thigh skin. Then, the vaginal incision and obturator groin skin incisions are closed.

In summary, the TVT-O sling is pulled through the levator ani muscles, the obturator internus and externus muscles, the adductor muscles and the groin skin. The trans-obturator anchoring requires that the polypropylene be in contact with the vaginal wall over the course of its full width, increasing area of the scar plate formed during healing. Over time, the combination of mesh shrinkage and scar plate formation will cause the anchoring points to pull towards the midline, causing pain at rest, with sexual intercourse, and with movements that activate the pelvic floor, obturator, and usually the adductor muscles. Trigger points in the levator ani muscles, caused by the puncturing, shrinkage, and scarring of the trans-obturator sling, can cause spasm of the levator ani muscles, elevating and sharpening the anorectal junction, causing bowel evacuation difficulties and pain due to outlet obstruction from the more acute nonrelaxing anorectal angle.

### **Summary**

As a fellowship trained specialist in Female Pelvic Medicine and Reconstructive Surgery, I have personally treated many women for complications related to transvaginal mesh repairs for pelvic organ prolapse and urinary incontinence. I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common mesh-related complications that I have

personally seen are pelvic pain, pain with intercourse, pain with movement, pain with sitting, painful scarring of the vagina and pelvic floor muscles and tissues, painful scar bands or scar plates in the vagina, pain radiating into the groin, buttocks and thighs, paresthesias in the groin, buttocks and thighs, non-healing surgical scars, mesh exposure with odorous vaginal discharge, mesh erosion into the pelvic organs, vaginal shortening and strictures, chronic inflammation of tissue, wadding or bunching up of the mesh in the vagina, and nerve entrapment.

When I evaluate, diagnose, and treat women with mesh-related complications, I usually rely on an interview with the patient, review of her personally documented history, review of her medical records, and a detailed clinical examination when possible. I use the information that I obtain from these modalities to determine the cause, treatment plan, and prognosis for the patient's presenting complaint. The documents I reviewed related to Iretta Ashbrook's case are attached as Exhibit 2.

### **Iretta Ashbrook Chronology**

#### Prior history

- Appendectomy 1986
- Knee surgery x 2 meniscal tear in 1990, 1991
- Breast Reduction 2004
- Thyroid disease

Nonsmoker, never smoked

12/16/2009 Pelvic ultrasound

Reason

- Vaginal bleeding and pain

Impression

Prominent endometrium 14 mm stripe  
3.2 cm left ovarian cyst

**10/29/2010: Procedure #1 (Dr. Viner)**

Diagnosis

Thickened endometrium by ultrasound  
Stress Urinary Incontinence  
Vulvar Lesions

Procedure

TVT transobturator  
Cystoscopy  
Hysteroscopy  
Dilation and Curettage  
Cautery Vaporization of vulvar lesion

Technique

Hysteroscopy, dilation and curettage performed in the standard fashion  
TVT-O  
Midurethral injection with lidocaine/epinephrine  
1 cm midurethral incision made  
Dissection carried to pubic ramus on each side.  
TVT-O needles placed in the usual fashion  
Cystoscopy revealed no foreign body or injury with a full bladder  
Scope was withdrawn  
Sling was adjusted until there was minimal to no leakage  
Elastic sleeves removed, and tape trimmed at skin level on both sides  
Incision closed with 2-0 Vicryl running  
Sterile dressings applied.  
Cautery used to vaporize hemangioma-type lesions on the vulva.  
Anesthesia reversed and patient returned to recovery room

2/2012 – Auto Crash

Sustained whiplash, scapula injury.

**6/14/2012: Procedure #2 (Dr. Case, Dr. Windisch)**

Diagnosis

Endometrial hyperplasia  
Sebaceous cyst  
Dyspareunia  
Stress incontinence

Procedure

Dr Case

- Excision Sebaceous cyst
- Hysteroscopy, D+C
- Dr. Windisch
  - Removal of trans-obturator vaginal sling
  - Cystoscopy
  - Placement of pubo-vaginal sling using Cadaveric fascia
  - Repliform

#### Technique

- Dr Case completed her portion of the procedure first
  - Dilation
  - Hysteroscopy,
    - Ashermans syndrome noted.
  - Curettage

#### Sling removal

- Vaginal speculum placed, Foley catheter placed
- Hydro-dissection of the anterior vaginal wall with dilute Marcaine
- Midline incision in anterior vaginal wall, several centimeters in length
- Sling located, and dissected laterally.
  - Sling noted to be "sopped in" close to the urethra
  - A tear in the urethra was noted while freeing up the sling
  - Closed with 3-0 Chromic suture
  - Watertight closure confirmed on cystoscopy

- Sling arms removed up to obturator membranes bilaterally

#### Pathology report

- Soft tissue from Transobturator space
  - Benign fibromuscular tissue
  - No mesh is identified
- Left Labial cyst
  - Benign Dermoid cyst
- Endometrial curettings
  - Weakly proliferative endometrium
  - Breakdown change
  - metaplasia

#### Pubovaginal sling placement

- 1 cm bilateral suprapubic incisions made
- Cadaveric sling made
  - 3 x 6 centimeter section of Cadaveric fascia was cut out
  - Prolene sutures were placed on each end of the fascia
- Stamey needles passed down
  - from the suprapubic stab wounds into the vaginal incision
  - on left and right
- Prolene sutures threaded into Stamey needles

Stamey needles pulled up with. Prolene sutures  
Cystoscopy was performed and no injury seen  
Space was held between fascia and bladder neck  
Prolene sutures were tied down  
Fascial sling stayed at the bladder neck  
Anterior vaginal wall closed with running 3-0 Chromic suture  
Suprapubic skin closed with monocryl subcuticular suture.

7/24/2012: Postop visit (Dr. Windisch)

Complaint

Soreness on left side, increased with activity  
Urinary dribbling and leakage, wearing pads

Impression

Scarring on left  
Bladder spasms and irritability

Plan

Increase physical activity  
Physical therapy

8/7/2012: Postop visit (Dr. Windisch)

Complaint

Doing much better  
Unable to sleep on her left side  
Left, Right sided lower abdominal pain  
Discomfort if does lot of sitting, walking around  
Taking Vesicare  
Got clearance from ophthalmologist due to Glaucoma)  
Noticed a huge difference in urgency/frequency  
Wearing a pad in day due to postvoid dribbling  
Has not used the Baclofen because not in that severe pain  
Starting Pelvic floor Physical Therapy next week.

Exam

PVR 64 ml  
Urine dip  
Negative leukocytes, nitrites  
No CVA tenderness on left, right

Plan

Not stated

9/11/2012: Office visit (Dr. Windisch)

Complaint

Urinary urgency  
Constipation  
Postvoid dribbling  
Attended 1 session of PT  
On Vesicare

Plan

B&O suppositories  
Vesicare 10 mg

12/6/2012: Office visit (Dr. Windisch)

Complaint

Urinary urgency  
Previously treated with  
Anticholinergics  
Baclofen  
Diet change  
Pelvic floor physical therapy

Dyspareunia

Leaking urine day and night  
Wearing pads all day

Severe Constipation

Blood in the urine

Presents for cystoscopy and urodynamics to evaluate things

Exam:

Tender left pelvic muscle  
Nontender right pelvic muscle  
Palpable scar tissue in area of prior sling  
Tender on left side, mild tenderness on right

Testing

Voiding diary  
3x nocturia, hourly frequency,  
urgency present with  
urination  
walking  
sitting  
sleeping

Urine dip  
Negative leukocytes, nitrites

Cystoscopy  
No abnormal findings

Urodynamics  
Normal postvoid residual  
Max Cystometric Capacity – 153 (low)  
Rectal spasm noted during filling  
Stress incontinence seen  
No urge incontinence seen

Diagnosis  
Pelvic floor dysfunction  
Hypertonicity of the detrusor  
Pain at prior sling site  
Stress incontinence

Plan  
Requested second opinion from Dr. Ballert

3/21/2013 Office Visit (Dr. Ballert)

Complaint  
Persistent, daily Stress and urge incontinence  
Persistent left groin pain and dyspareunia  
2 UTI in the past 6-8 months  
One episode of gross hematuria with a uti  
Treated with multiple anticholinergics and baclofen  
Did not find these helpful

Exam  
Tenderness at midurethra, palpable scarring  
Levator muscles tender on right and left

Assessment  
Urinary incontinence  
Urge and Stress incontinence  
Urinary urgency

Plan  
Cystoscopy to look for foreign body in the bladder

5/21/2013 Office Procedure Visit (Dr. Ballert)

Procedure  
Cystoscopy  
Bladder appeared normal  
Urodynamics  
MCC was 214 ml  
DO demonstrated with leakage

SUI demonstrated with cough at 214 ml

Plan

Sling takedown offered

Patient to see her gynecologist re: concurrent oophorectomy

8/7/12- 4/30/13 Bauman Physical Therapy.

Diagnosis

Left inguinal pain

PFD

Scar tissue at 9-12 O'clock position

Dyspareunia

Constipation

Therapy

Physical Therapy for Left Inguinal Pain

Abdomen

Pelvic floor

Discharged:

4/30/13

50% achievement of Short term goals

7/28/14 – CT Abdomen/Pelvis

Reason

Left Flank Pain

Worsening left lower quadrant pain

Impression

Moderate Diverticulitis of descending colon

No reason for hematuria identified

11/30/2015: Procedure #3 (Dr. Reynolds)

Diagnosis

Mixed Urinary Incontinence

Bladder neck obstruction

Procedure

Revision of synthetic sling

Autologous rectus fascial sling

Cystoscopy

Urethrolisis

Technique

Rectus fascial harvest

Pfannenstiel skin incision was made and dissected to fascia

8 cm x 1.5 cm piece of rectus fascia harvested for the sling

Fascial incision closed

#1 PDS placed on either end of the sling.

#### Vaginal Portion

Lone Star retraction

U shaped incision under bladder neck

U shaped flash dissected off the endopelvic fascia

Mesh sling identified in the midline

Tight band across the bladder neck

Dissected from the underlying endopelvic fascia

Incised in the midline

Dissected into bilateral obturator fascia

Mesh arms truncated and removed from the field

Bladder drained

Space of Retzius entered and developed bluntly bilaterally

Stamey needles passed top to bottom into vaginal incision

Cystoscopy performed

no perforation seen

Urethra patulous

Urine leaked around the scope during cystoscopy

Bladder neck and urethra clear

Sling sutures pulled up bilaterally

Sling tagged to urethra with 4-0 Vicryl Suture

Vaginal wall closed with 3-0 Vicryl Suture

#### Sling tensioning

To urethral coaptation,

2 finger breadths between knot and fascia

Spontaneous urethral leakage stopped after tiedown

#### Skin incision closed

Deep and superficial Vicryl sutures

Steri-strips placed

#### Pathology report

Vaginal mesh, 2 pieces

Dimensions

#1 3.5 x 0.5 x 0.4 cm

#2 2.1 x 0.5 x 0.5 cm

Dense fibroconnective tissue

3/25/2016 Office Visit (Dr. Poulouse – General Surgery)

#### Complaint

Left sided groin pain since December, 2015

Impression

- Reviewed the CT images
- Difficult to appreciate an inguinal hernia in the left inguinal region
- Chronic pain is not due to hernia, more consistent with neuropathic pain
- Recommended physical therapy

4/15/2016 Office Visit (Dr. Reynolds)

Complaint

- Left inguinal and mons pubis pain
- Urinary incontinence
- No relief from 4 sessions of PT.

Exam

5/2/2016 Office procedure Visit (Dr. Reynolds)

Complaint

- Inguinal pain
- Urinary incontinence

Test

- Urodynamics
  - Detrusor overactivity incontinence
  - Stress incontinence
  - PVR 0 ml

Cystoscopy

- Normal bladder mucosa,
- Clear efflux from bilateral ureteric orifices

Diagnosis

- Overactive bladder, Detrusor Overactivity
- Mixed urinary incontinence.

8/10/2016: Procedure #4 (Dr. Reynolds)

Diagnosis

- Overactive Bladder
- Mixed urinary incontinence

Procedure

- Cystourethroscopy with instillation
- Botox injection of bladder

Technique

- Cystoscopy performed
  - No abnormal findings
- Botox injection
  - 100 units injected into detrusor muscle

12/14/2016: Procedure #5 (Dr. Reynolds)

Diagnosis

- Urge incontinence
- Abnormal Uterine Bleeding

Procedure

- Cystourethroscopy
- Botox injection of bladder
- Exam under anesthesia

Technique

- Cystoscopy performed
  - No abnormal findings
- Botox injection
  - 150 units injected into detrusor muscle
- Exam under anesthesia
  - Speculum placed, vagina and cervix visualized
  - No abnormalities noted

4/27/2017: Procedure #6 (Dr. Reynolds)

Diagnosis

- Overactive bladder
- Urge urinary incontinence

Procedure

- Cystourethroscopy
- Botox injection of bladder

Technique

- Cystoscopy performed
  - No abnormal findings
- Botox injection
  - 150 units injected into detrusor muscle

9/30/17 Office Visit (Dr. Betsy Reynolds – Primary care)

Complaint

- Vaginal itching
- Burning on urination

Treatment

- Cipro 500 bid x 10 days
- Pyridium
- Diflucan

**2/6/2018: Procedure #7 (Dr. Reynolds)**

Diagnosis

Urge urinary incontinence

Procedure

Cystourethroscopy

Botox injection of bladder

Technique

Cystoscopy performed

No abnormal findings

Botox injection

150 units injected into detrusor muscle

**9/11/2018: Procedure #8 (Dr. Reynolds)**

Diagnosis

Urge urinary incontinence

Procedure

Cystourethroscopy

Botox injection of bladder

Technique

Cystoscopy performed

No abnormal findings

Botox injection

150 units injected into detrusor muscle

**11/1/2018 Office Visit (Dr. William Reynolds)**

Complaint

Worsened incontinence following last Botox injection (9/2018)

Increased pad use, constantly wet

Constipation

Managed with Docusate

Left Groin pain, paresthesia

Testing

PVR 300 cc by catheterization

CT scan without explanation of her pelvic pain

Plan

Teach Self catheterization

Continue vaginal estrogen

Continue Docusate for Constipation

**4/5/2019 Office Visit (Dr. Betsy Reynolds)**

Complaint

Wellness exam  
Reports cathing 5-6 times daily  
Chronic pelvic pain  
Overactive bladder  
Stress incontinence  
Plan  
Being followed at Vanderbilt for pelvic floor issues.

### **Postoperative Pelvic Floor symptoms**

New symptoms since TVT-O

Urinary retention

(Urinary incontinence, also pre-procedure)

Recurrent vaginal pain

Recurrent UTI

Rectocele

Dyspareunia

Chronic constipation

Iretta Ashbrook underwent a Gynecare Trans-Obturator sling procedure in 2010 to address her stress urinary incontinence. Following that surgery, she developed pain with sexual intercourse, and continued to have stress urinary incontinence. These bothersome symptoms caused her to seek additional care, and she then underwent a procedure to remove the transobturator sling, and place a retropubic pubovaginal cadaveric sling by another surgeon. Iretta Ashbrook developed left sided pain in the lower abdomen and pelvis, with continues urinary dribbling and leakage. She was diagnosed with painful scarring on the left, and bladder irritability and spasms. The pain and bladder symptoms persisted, and she was started on Vesicare, but her dribbling symptoms continued and she was

referred out for physical therapy. She continued to complain of dyspareunia and also developed severe constipation, and had blood in her urine. She was diagnosed with tender pelvic floor muscles and scarring in the vagina in the area of the prior sling. Her testing showed low bladder capacity, rectal spasms and stress urinary incontinence. She was evaluated by a third surgeon who determined that she had detrusor overactivity with incontinence, and stress incontinence. She was offered a takedown of the remnants of her Gynecare TVT-Obturator sling.

She was evaluated and treated by a physical therapist, who determined that she had left groin pain, pelvic floor dysfunction, painful scar tissue in the vagina, pain with intercourse, and constipation.

Iretta Ashbrook sought care from a fourth surgeon, who determined that she had mixed urinary incontinence, and bladder neck obstruction, in addition to her other pelvic floor symptoms. She underwent a third surgical procedure for revision of her synthetic TVT-Obturator sling, and placement of an Autologous Rectus Fascial Sling with urethrolysis. During that procedure, the surgeon located and retrieved mesh from under the bladder neck. The surgeon reported that the mesh was positioned tightly in place under the bladder neck in an obstructive way. The mesh arms were dissected out to their insertion points in the obturator internus muscles bilaterally, and excised at the insertion points. Iretta Ashbrook continued to complain of left groin pain, and was evaluated by a general surgeon for a possible inguinal hernia to explain her persistent left groin pain. That surgeon did not believe that her small left inguinal hernia explained her groin pain, and suggested that she

undergo physical therapy to address musculoskeletal issues causing her left groin pain.

Following the mesh explantation and Autologous Fascial sling, Iretta Ashbrook continued to have urinary incontinence, and left groin pain, unresponsive to anti-inflammatory medications, Neurontin, and physical therapy. She was offered and failed trials of two different types of bladder control medication, specifically Myrbetriq and Oxybutynin. She then underwent a fourth surgery in 8/10/2016, where she had 100 Units of Botox injected into her bladder muscle. This failed to resolve her incontinence, and she then underwent a 5<sup>th</sup> surgery to inject an increased amount (150 Units) of Botox injected into her bladder muscle. Her Urge incontinence symptoms persisted, and she underwent 3 additional procedures for botox injections into the bladder, to address her urinary incontinence. Following the 5<sup>th</sup> botox injection, her urinary incontinence worsened, her pad use increased, she reported being constantly wet, and she in urinary retention. She was taught clean intermittent self-catheterization. She was also noted to be having issues with constipation.

On evaluation by her primary care physician in 4/5/2019, Iretta Ashbrook reports: urinary retention, needing to self-catheterize herself 5-6 times daily, chronic pelvic pain, groin pain, pain with intercourse, constipation, overactive bladder, and stress incontinence. She also sustained multiple bladder infections, and had episodes of vaginal bleeding.

Iretta Ashbrook had stress urinary incontinence before implantation of the Gynecare TVT-Obturator sling. She did not have urinary retention, chronic pelvic pain, groin pain, pain with intercourse, constipation, overactive bladder, or recurrent bladder infections. Before the TVT-Obturator implant she was not constantly wet.

In the nine years after her Gynecare TVT-Obturator surgery, Iretta Ashbrook required 7 additional surgical interventions to address complications caused by the Gynecare TVT-Obturator mesh product. Despite 2 revision attempts, 2 retropubic sling placements, and 5 bladder botox injection procedures, Iretta Ashbrook continues to have worsened bladder incontinence, and has since developed urinary retention, chronic pelvic pain, groin pain, pain with intercourse, constipation, overactive bladder, and recurrent bladder infections.

Despite the 2 revision attempts, Iretta Ashbrook still has the arms of the Gynecare TVT-Obturator sling embedded and scarred into her groins on both sides of her body.

### **Differential Diagnosis**

In determining the cause of a specific injury, the process of "differential diagnosis" is applied to identify potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

This process of differential diagnosis, or differential etiology, is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case.

Prior to her Gynecare TVT-Obturator surgery, Iretta Ashbrook had a history of appendectomy, knee surgery for meniscal tears, breast reduction, and thyroid disease, as well as a thickened endometrial lining. She did not have urinary retention needing to self-catheterize herself 5-6 times daily, chronic pelvic pain, groin pain, pain with intercourse, constipation, overactive bladder with incontinence. She never smoked tobacco.

None of her pre-existing conditions or surgeries involved the placement of synthetic mesh into the vagina. None of the above conditions are recognized as being risk factors for urinary retention, chronic pelvic pain, groin pain, pain with intercourse, constipation, overactive bladder with incontinence.

Iretta Ashbrook's complaints of chronic pelvic pain, groin pain, pain with intercourse, constipation, overactive bladder with incontinence began after implantation of the Gynecare TVT-O mesh device. Her urinary retention came after repeated bladder botox injections which were done to try and treat the overactive bladder symptoms caused by the TVT-Obturator device.

Her pelvic pain and dyspareunia started after placement of the TVT-Obturator device, and this symptom is unquestionably directly attributable to the placement of

the mesh sling arms into the pelvic floor and obturator muscles because there is no other credible explanation. Ms Ashbrook had was in an auto crash in February 2012, but her reported injuries were limited to whiplash and a scapula injury, neither of which involve the pelvic organs. She had vulvar lesions cauterized during her TVT-Obturator placement, but this did not involve the vaginal tissues, and cannot be the cause of her vaginal pain. This leaves the Gynecare TVT-Obturator sling as the only cause of her debilitating pelvic floor symptoms. The sling scarred into the pelvic floor muscles and vaginal wall, and shrunk, thereby pulling on the pelvic sidewall muscles, causing her pain at rest, exacerbated by intercourse. Also, the pain caused by the shrunken, scarred in sling mesh leads to spasm of the pelvic floor muscles, which then sharpens the anorectal angle, causing constipation.

Iretta Ashbrook required 2 additional attempts to remove the vaginal portion of her TVT-Obturator sling arms, but the arms of the sling remain embedded and scarred into her left and right groins and are the more likely than not cause of her left sided groin pain. I have personally seen women like Iretta Ashbrook with groin pain caused by the remaining arms of partially explanted TVT-Obturator type slings. I have personally seen that, because of the presence of the scarred in mesh arms, these women cannot be cured with physical therapy alone, but require complete explantation of the embedded mesh arms before physical therapy can be successful in releasing the muscle spasm caused by the scarring from the mesh.

In my surgical experience, Trans-Obturator mesh complications like those seen in Iretta Ashbrook are difficult to treat, and complete removal of the scarred-in mesh remnants represents a significant surgical challenge, which carries risks of

blood loss, as well as nerve and urinary system damage, and substantial scarring of the vaginal and groin tissues.

Iretta Ashbrook's urinary incontinence worsened after placement of the Gynecare TVT-O sling. Her incontinence symptoms prompted intervention in which 2 retropubic slings were placed on separate occasions to try to correct her stress incontinence, both without relief of her urinary incontinence. Her severe urge incontinence also prompted treatment with anticholinergic medications and bladder botox injections, all without relief. Her urinary retention is likely the result of the botox injections, which were performed to attempt to address her urge incontinence. The retropubic slings, mesh explantation, and botox interventions were performed in an attempt to try to address the postoperative problems caused due to the placement of the Gynecare TVT-Obturator sling and are therefore complications attributable to the TVT-Obturator sling.

Iretta Ashbrook's TVT-Obturator implantation was performed using acceptable surgical practice, and in accordance with the Gynecare TVT-Obturator IFU. In my opinion, her chronic pelvic pain, groin pain, and dyspareunia occurred because of the scarring of the of the Gynecare TVT-Obturator mesh into the anterior vaginal wall and pelvic floor, obturator, and groin tissues, followed by post implantation contraction of the TVT-Obturator mesh, which placed traction on the pelvic floor, obturator, and groin muscles and tissues.

These complications experienced by Ms. Ashbrook from her Gynecare TVT-Obturator vaginal mesh are similar to complications that I have personally seen in

other women who have come to me for treatment of painful, contracted TVT-Obturator slings.

Like Iretta Ashbrook, many of these affected women require multiple surgical and other therapeutic interventions in order to improve their symptoms to a level that they are able to live with. Despite multiple surgical, medication, and physical therapy interventions, some of these women will never be cured of their mesh induced symptoms.

**Opinion:**

So far, in addition to the sling implantation surgery, Iretta Ashbrook has required 7 additional surgeries to address complications caused by her TVT-Obturator Sling. Ms. Ashbrook still has sling mesh arms remaining in her groin tissues on her left and right sides. Iretta Ashbrook's mesh complications of chronic pelvic pain, groin pain, chronic dyspareunia, and constipation and would not have occurred with a native tissue repair like the Burch colposuspension, or a retropubic sling.

In my opinion, the prognosis for Ms. Ashbrook's persistent groin pain, pelvic pain, constipation, and urinary incontinence is uncertain. This is because the vaginal scarring caused by the mesh placement, and the 2 explantation and retropubic sling surgeries that she endured, will make subsequent repairs more difficult and less likely to be effective.

Ms. Ashbrook did not get relief from her urge incontinence, with anticholinergic or beta-agonist medications, nor did she get relief from 5 episodes of

detrusor botox injections. She may be a candidate for sacral neuromodulation, which has a chance of improving her urge incontinence, after the urinary retention from the botox injections resolves over time.

As far as Iretta Ashbrook's chronic pelvic pain, groin pain, and pain with intercourse is concerned, she has not had relief from a course of vaginal estrogen or pelvic floor physical therapy. This makes vaginal atrophy an unlikely cause of her dyspareunia. It is more likely than not that her pain with intercourse and her vaginal pain are due to the vaginal wall scarring from her Gynecare TVT-Obturator, and her subsequent surgeries to remove the spanning mesh. Her vaginal wall tenderness and scarring on exam is documented by Dr. Ballert, as well as her pelvic floor physical therapist.

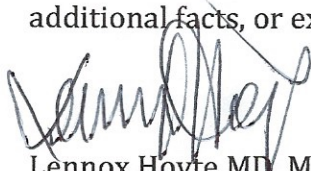
Regarding her intractable left groin pain, this is not caused by her retropubic fascial sling because the fascial sling dissection involved the fascia overlying the rectus abdominis muscles in the lower abdomen. In my abundant surgical experience in performing Autologous rectus fascial slings, this rectus fascial dissection can sometimes cause rectus muscle trigger points leading to transient suprapubic pain which is readily cured with trigger point injections and directed physical therapy, but it does not cause groin pain. As her general surgeon Dr. Poulouse pointed out, her groin pain is not caused by her very small left inguinal hernia. This leaves the painful scarring from the remaining shrunken Gynecare TVT-Obturator sling arms scarred into her obturator and adductor muscles and groin tissues as the only cause of Iretta Ashbrook's intractable groin pain.

Iretta Ashbrook did not complain of constipation before her Gynecare TVT-Obturator surgery. Her medical record does not show any documentation of a significant rectocele, and this removes a rectocele as possible cause of her constipation. Her medical record does have documentation of pelvic floor dysfunction and levator tenderness after her Gynecare TVT-Obturator sling placement, but she did not have pelvic floor dysfunction before her Gynecare TVT-Obturator mesh implantation. As noted elsewhere in this report, more likely than not, Iretta Ashbrook's constipation is therefore caused by painful spasm of the levator ani muscles, which sharpens the anorectal angle, causing her difficulties with stool evacuation. In the absence of a persistent source of pain, this kind of levator spasm is treatable with myofascial release pelvic floor physical therapy, and Ms. Ashbrook had many of these PT sessions without relief. This leaves the painful scarring of the levator ani muscles caused by the passage of the Gynecare TVT-Obturator sling as the only remaining cause of Iretta Ashbrook's chronic constipation.

The Gynecare TVT-Obturator IFU does not appropriately disclose the risks of their products. A patient cannot adequately give informed consent unless they are given all of the medical facts accurately by their physician to have an adequate picture of the risk profile they are consenting to. The physician cannot adequately give them all of the necessary information unless it is provided by the manufacturer in the IFU. The manufacturer of a permanent medical device implant is in the best position to know all of the risks and must disclose all of the risks known to it and

give a fair depiction of the risk profile of the device. Gynecare failed to warn physicians and patients about numerous complications it knew or should have known, including the following: Chronic pain, groin pain, chronic dyspareunia that may never resolve, need for multiple revision surgeries to address bothersome mesh related symptoms, inability to remove all of the mesh, mesh shrinkage, small painful scar plate formation, mesh contraction, urinary and fecal dysfunction, reduced efficacy of future SUI procedures.

All of my opinions are made to a reasonable degree of medical certainty. I reserve the right to amend or supplement these opinions based on new information, additional facts, or examination findings.

A handwritten signature in black ink, appearing to read "Lennox Hoyte", is written over the printed name.

Lennox Hoyte MD, MSEECS  
8/3/2019